

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Thomas A. ALHEIDT

Art Unit: 3767

Application No.: 10/530,817

Examiner: Schell, Laura C.

Filed: April 8, 2005

Confirmation No.: 9959

For: Flush Syringe Having Anti-Reflux Features

Atty. Docket No.: P-5856

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal for the subject application filed on February 22, 2011, a brief in support of the appeal is now submitted. Submission of a brief in support of the appeal in this case is due by April 22, 2011. Accordingly, this paper is timely filed.

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REAL PARTY IN INTEREST

The real party in interest is Becton, Dickinson and Company, the assignee of record.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that are related to this appeal, or which will affect or have a bearing on this appeal.

STATUS OF CLAIMS

Claims 4-6 and 18-23 were finally rejected in an Office Action mailed on November 22, 2010, and are the subject of this appeal. Claims 7-17 were previously cancelled without prejudice or disclaimer.

STATUS OF AMENDMENTS

No claims have been amended, cancelled or added subsequent to the Final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter encompasses an intravenous (I.V.) flush syringe assembly.

Independent claim 4 is directed to an I.V. flush syringe assembly **120** comprising:

a barrel **122** having an inside surface **132** defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface having a contact area **162** at the distal end of said barrel **122**, said contact area **162** being a roughened portion of said inside surface, (*page 3, paragraphs [0008] and [00010]; page 8, paragraph [00030]*).

a plunger **24** including an elongate body portion having a proximal end, a distal end and a flexible stopper **54** slidably positioned in fluid-tight engagement with said inside surface of said barrel **122** for drawing fluid into and driving fluid out of said chamber by movement of said stopper **54** relative to said barrel **122**, said elongate body portion extending outwardly from said open proximal end of said barrel **122**; (*page 3, paragraph [0008]*).

wherein said contact area **162** has a higher coefficient of friction than said inside surface outside of said contact area **162** for frictionally engaging said stopper **54** when said stopper **54** is in contact with said distal wall of said barrel **122** for frictionally holding said stopper **54** in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber, (*page 3, paragraphs [0008] and [00010]; page 8-9, paragraph [00030]*).

wherein the diameter of the outer surface of each portion of the stopper **54** is less than or equal to the largest diameter of the inside surface of the distal end of the barrel **122** having the contact area **162** when the stopper **54** is in the partially deflected position. (*page 8, paragraph [00030] and Fig. 9*).

The dependent claims are directed to various embodiments of the disclosed syringe assembly and needle shield assembly. In particular, dependent claim 5 is directed to the I.V. flush syringe assembly **120** of claim 4 wherein the contact area **162** further includes a plurality of annular deformations. (*page 3, paragraph [00010]*). Dependent claim 6 is directed to the I.V.

flush syringe assembly **120** of claim 5 wherein the annular deformations are annular projections on said inside surface of the barrel **122**. (*page 3, paragraph [00010]*).

A copy of the appealed claims is appended hereto, beginning at page 15.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 4-6 and 23 are unpatentable under 35 USC 102(b) as anticipated by Laffy (US Patent No. 5,373,971).
2. Whether claims 18-21 are unpatentable under 35 USC 103(a) as obvious over Laffy (US Patent No. 5,373,971) in view of Lynn (US Patent No. 5,522,804).
3. Whether claim 22 is unpatentable under 35 USC 103(a) as obvious over Laffy (US Patent No. 5,373,971) in view of Greenwood (US Patent No. 5,120,314).

ARGUMENT

SUMMARY OF THE ARGUMENT

Appellants respectfully set forth this appeal brief on the following grounds, among other grounds.

First, the conclusion of anticipation fails to establish that every element of independent claim 4 is expressly or inherently described in Laffy (US Patent No. 5,373,971).

Second, the conclusion of anticipation by Laffy specifically fails to establish express or inherent description in Laffy of annular deformations and annular projections in the contact area, as recited in dependent claims 5 and 6.

Third, the conclusion of obviousness fails to overcome the deficiencies of primary reference Laffy, as the secondary references do not provide teaching or suggestion of the claim elements missing from Laffy.

I. Rejection Under 35 USC 102(b) As Anticipated by Laffy (US Patent No. 5,373,971)

Claims 4-6 and 23 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Laffy et al. (US 5373971). According to the Examiner, Laffy discloses a syringe capable of being used as an IV flush syringe which includes an inside surface having a contact area at the distal end of the barrel which is roughened. The “roughened” portion is alleged to be the notches or teeth formed on the inside surface of the barrel which will dig into the plunger stopper and prevent it from moving rearwardly once it has been advanced. *Referencing feature 10 of Figs. 10 and 11, and col. 8, ln. 66-col. 9, ln3 of Laffy; See page 3, lines 15-22 of the Final Office Action mailed 11/22/2010.* It is also alleged that this contact area has a higher coefficient of friction than the inside surface outside the contact area for frictionally engaging the stopper when the stopper is in contact with the distal wall of the barrel for frictionally holding the stopper in a partially deflected position to prevent reflux. *See page 3, lines 11- 15 of the Final Office Action mailed 11/22/2010.*

“[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In

addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But disclosure of each element is not quite enough – this court has long held that '[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.*'") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original)).

Applicants submit that Laffy does not expressly or inherently teach the claimed roughened surface which frictionally engages the stopper when the stopper is in contact with the distal wall of the barrel for frictionally holding the stopper in a partially deflected position to prevent reflux, and therefore does not anticipate independent claim 4. The Examiner's characterization of the reference with respect to holding the plunger and preventing reflux is incorrect. Laffy describes the non-return means, such as projections, as downwardly oriented teeth, catches, or notches provided on the inner surface of the lateral wall and blocking the piston against any movement toward the upper open end of the body of the container. *Col. 3, lns. 24-33 of Laffy, emphasis added.* Laffy specifically describes the notches or teeth shown in Fig. 10 as being "oriented in the direction of the outlet orifice, so as to oppose any movement of the piston 4 in the opposite direction and block it in the position attained." *Col. 8, ln. 66-col. 9, ln. 3 of Laffy, emphasis added.* The description of the notches or teeth being oriented toward the outlet orifice (i.e., in a distal direction) teaches that they act as barbs which allow the piston to slide over them in the forward or distal direction but then dig into the piston to prevent subsequent rearward or proximal motion.

The description of the notches or teeth as "blocking" the piston in the position attained teaches that they create a physical barrier to prevent rearward movement. That is, the notches or teeth project into the container on an angle from its inside surface to create a section which is narrower than the width of the plunger. The angle of the teeth/notches permits the plunger to slide over the teeth/notches in the forward direction but causes them to dig into the plunger to prevent its rearward movement. These teachings confirm that Laffy's notches and teeth function by physically blocking or capturing the piston.

Capturing the piston using directionally-oriented notches or teeth in the container, as in Laffy, does not involve frictional engagement to hold the stopper in a deflected position to prevent reflux as required by claim 4. There may arguably be some increased friction as the plunger slides forward over the teeth/notches. However, the force exerted to prevent subsequent rearward movement of the piston (i.e., the movement that would otherwise cause reflux) is a purely mechanical force exerted axially in a direction opposing such movement which occurs as a result of the physical digging of the angled teeth/notches into the piston. Laffy therefore fails to expressly or inherently teach each and every element as set forth in claim 4.

Claims 5, 6 and 23 each depend ultimately from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). Accordingly, claims 4-6 and 23 are also not anticipated by Laffy.

The rejection of claims 4-6 and 23 for anticipation is improper and should be reversed.

II. Rejection of Claims 5 and 6 As Anticipated by Laffy (US Patent No. 5,373,971)

In addition to the arguments presented in Section I above, Applicants submit additional arguments separately applied to claims 5 and 6. Claim 5 further defines the contact area of claim 4 (i.e., the roughened portion at the distal end of the barrel) to include a plurality of annular deformations. Claim 6 further defines the annular deformations of claim 5 as annular projections on the inside surface of the barrel.

In rejecting claim 5 as anticipated by Laffy, the Examiner points to the teeth/notches shown in Figs. 10 and 11 of the reference as support for annular deformations. In rejecting claim 6 as anticipated by Laffy, the Examiner points to the same teeth/notches shown in Figs. 10 and 11 as support for the annular deformations being annular projections. *Page 4, lines 6-10, of the Final Office Action.* Figs. 10 and 11 clearly show the projections as individual, distally-oriented teeth. Further, in contrast to the Examiner's interpretation, the representations of Figs. 10 and 11 show only two vertical rows of teeth/notches on the inside of the container. There is nothing in Figs. 10 or 11 or elsewhere in Laffy to suggest any kind of annular arrangement of the teeth or notches.

Accordingly, claim 5 is not anticipated for the additional reason that Laffy does not teach or suggest annular deformations on the inside wall. Claim 6 is not anticipated for the additional

reason that Laffy does not teach or suggest annular projections on the inside wall. These are further reasons that the rejection of claim 5 and claim 6 for anticipation is improper and should be reversed.

III. Rejection Under 35 USC 103(a) As Obvious Over Laffy (US Patent No. 5,373,971) in view of Lynn (US 5522804)

Claims 18-21 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laffy et al. (US 5373971) in view of Lynn (US 5522804). Lynn is relied upon for disclosure of a flush syringe with a tip cap and flushing solution in the chamber of the syringe, wherein the flushing solution is saline. Lynn is further relied upon for disclosure of a needle assembly attached to the end of the syringe. *See page 5, lines 9-18 of the Final Office Action mailed 11/22/2010.* It is allegedly obvious to modify Laffy with these features as taught by Lynn.

None of the teachings referenced in Lynn overcome the failure of Laffy, discussed above, to disclose frictionally engaging the stopper to frictionally hold it in a deflected position to prevent reflux. *Prima facie* obviousness has therefore not been established with respect to claims 18-21. The rejection is improper and should be reversed.

IV. Rejection Under 35 USC 103(a) As Obvious Over Laffy (US Patent No. 5,373,971) in view of Greenwood (5,373,971)

Claim 22 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laffy et al (US 5373971) in view of Greenwood (US 5120314). Greenwood is relied upon for disclosure of a stopper made from rubber. *See page 6, lines 1-6 of the Final Office Action mailed 11/22/2010.* It is allegedly obvious to modify Laffy with the stopper of Greenwood.

None of the teachings of Greenwood overcome the failure of Laffy to disclose frictionally engaging the stopper to frictionally hold it in a deflected position to prevent reflux. *Prima facie* obviousness has therefore not been established. The rejection is improper and should be reversed.

CONCLUSION

For the foregoing reasons, Appellants submit that claims 4-6 and 18-23 are not unpatentable over Laffy (US 5373971); are not unpatentable over Laffy (US 5373971) in view of Lynn (US 5522804), and; are not unpatentable over Laffy (US 5373971) in view of Greenwood (US 5120314). Reversal of the Examiner's rejections is therefore appropriate and respectfully solicited.

Respectfully submitted,

Date: April 20, 2011

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CLAIMS APPENDIX

4. An I.V. flush syringe assembly comprising:

a barrel having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface having a contact area at the distal end of said barrel, said contact area being a roughened portion of said inside surface,

a plunger including an elongate body portion having a proximal end, a distal end and a flexible stopper slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel;

wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber,

wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position.

5. The syringe assembly of claim 4 wherein said contact area further includes a plurality of annular deformations.

6. The syringe of claim 5 wherein said annular deformations are annular projections on said inside surface of said barrel.

18. The syringe assembly of claim 4 including flush solution in said chamber.

19. The syringe assembly of claim 18 further including a tip cap releasably connected to said tip of said syringe barrel for sealing said passageway.

20. The syringe assembly of claim 18 wherein said flush solution is selected from the group consisting of saline flush solution and heparin lock flush solution.

21. The syringe assembly of claim 4 further comprising a needle assembly including a cannula having a proximal end, a distal end and a lumen therethrough, and a hub having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber.

22. The syringe assembly of claim 4 wherein said stopper is made from material selected from the group consisting of thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof.

23. The syringe assembly of claim 4 wherein said stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.